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Mammographie-Screening in der Brustkrebsfrüherkennung: Aktuelle Internationale Ergebnisse und die Umsetzung in Deutschland

Mammography Screening between Efficacy and Effectiveness

Dr. B.Gibis, MPH

Kassenärztliche Bundesvereinigung, Berlin

Terminology

Factors influencing effectiveness (with a special focus on Germany)

Conclusions

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Efficacy: effects of an intervention under ideal conditions

Effectiveness: effects of an intervention under routine conditions

Intervention: health related specific intervention (diagnostic or therapeutic or combined), program or other

Effects: ideally outcomes

Intention-To-Treat Model

Efficacy v. Effectiveness

An <u>efficacious</u> treatment is one that is proven better than an alternative <u>for those who receive it</u>. ("works in theory")

An <u>effective</u> treatment is is one that is proven better than an alternative <u>for those to whom it is offered</u>. ("works in practice")

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Efficacy of mammography screening: Hackshaw et al 2003

Tab. 5.1 Randomisierte, kontrollierte Studien mit Mammograpie als alleiniger Screeningmethode und ungescreenter Kontrollgruppe (nach Hackshaw 2003)						
Studie	Screeningint ervall (in Monaten)	Anspruchsbe rechtigtes Alter	Anzahl eingeladener Frauen	Durchschnittl iche Follow-up-Zeit (in Jahren)	Gesamtzahl der Todesfälle an Brustkrebs in der Studie	Relatives Mortalitätsris iko für Brustkrebs (95% CI)
New York	12	40–64	31.000	10	228	0,71 (0,55–0,91)
Edinburg	24	45–64	23.000	10	217	0,85 (0,65–1,12)
Schweden						
„Two-county"	24, 33	40–74	77.000	11	481	0,78 (0,65–0,93)
Malmö	18–21	45–70	21.000	9	195	0,81 (0,62–1,07)
Stockholm	28	40–65	39.000	7	93	0,76 (0,50–1,14)
Göteborg	18	40–59	21.000	5	74	0,81 (0,50–1,29)
Schweden zusammeng efasst	–	–	–	–	–	0,77 (0,67–0,88)
Alle Studien	–	40–74	212.000	–	1.288	0,78 (0,70–0,87)

Considerable Heterogeneity of RCTs

- Age
- RCT-Design issues (randomization, type of control group)
- radiographic equipment
- screening-processes (such as double reading)
- screening-interval
- recruitment/participation rates

The German way…

28. 06. 2002: Der Bundestag beschließt einstimmig:

Die Spitzenverbände der Krankenkassen und die Kassenärztliche Bundesvereinigung sollen bis zum Jahr 2003 die Voraussetzungen für ein flächendeckendes Screening-Programm nach Europäischen Leitlinien schaffen, das durch zertifizierte Mammographie-Einrichtungen durchgeführt wird.

BMG   BfD   AOLG   NAR   oberste Landesbehörden   LA RöV   EUREF

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Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit

Bundesministerium für Umwelt, zuständig für Röntgenverordnung

Im Normalfall einer Röntgenuntersuchung entscheidet der Arzt, dass bei einem Patienten zur Abklärung eines individuellen Befundes Röntgenstrahlung angewendet wird (rechtfertigende Indikation nach § 23 RöV).

Röntgenreihenuntersuchungen zur Brustkrebs-Früherkennung stellen eine Anwendung außerhalb der Heilkunde im engeren Sinne dar. Solche Untersuchungen müssen nach § 25 RöV gesondert zugelassen werden.

| BMG | BfD | AOLG | NAR | oberste Landesbehörden | LA RöV | EUREF |

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European Guidelines (4th edition): no singular, ideal (ecclectic) way of screening, but description of a pathway

Sensitivity/specificity: UK, Netherlands
Recallrate: UK/USA
Double reading (Mammography and Pathology)
Number of views (1 or 2 two per breast)
Invitation system

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Factors influencing effectiveness

Starting position: could be worse...

Lymphnode status and Tumours < 20mm (incident round)

	No	In situ und/oder < 20mm
European guidelines (4th edition)	> 75%	80%
Germany before Screening (Girsiepen et al. 2004)	57,6%	53,1%
Modellprojekte (Kääb et al. 2006)	87,2 (-100%)	78,7%
Netherlands (Otto et al. 2003)	67%	78%
UK (Sasieni 2003)	75%	63% (15mm)

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Starting position: could be worse...

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SDR, Malignant neoplasm of breast, per 100000

Legend:
- Austria
- Finland
- France
- Germany
- Italy
- Netherlands
- Spain
- Sweden
- Switzerland
- United Kingdom

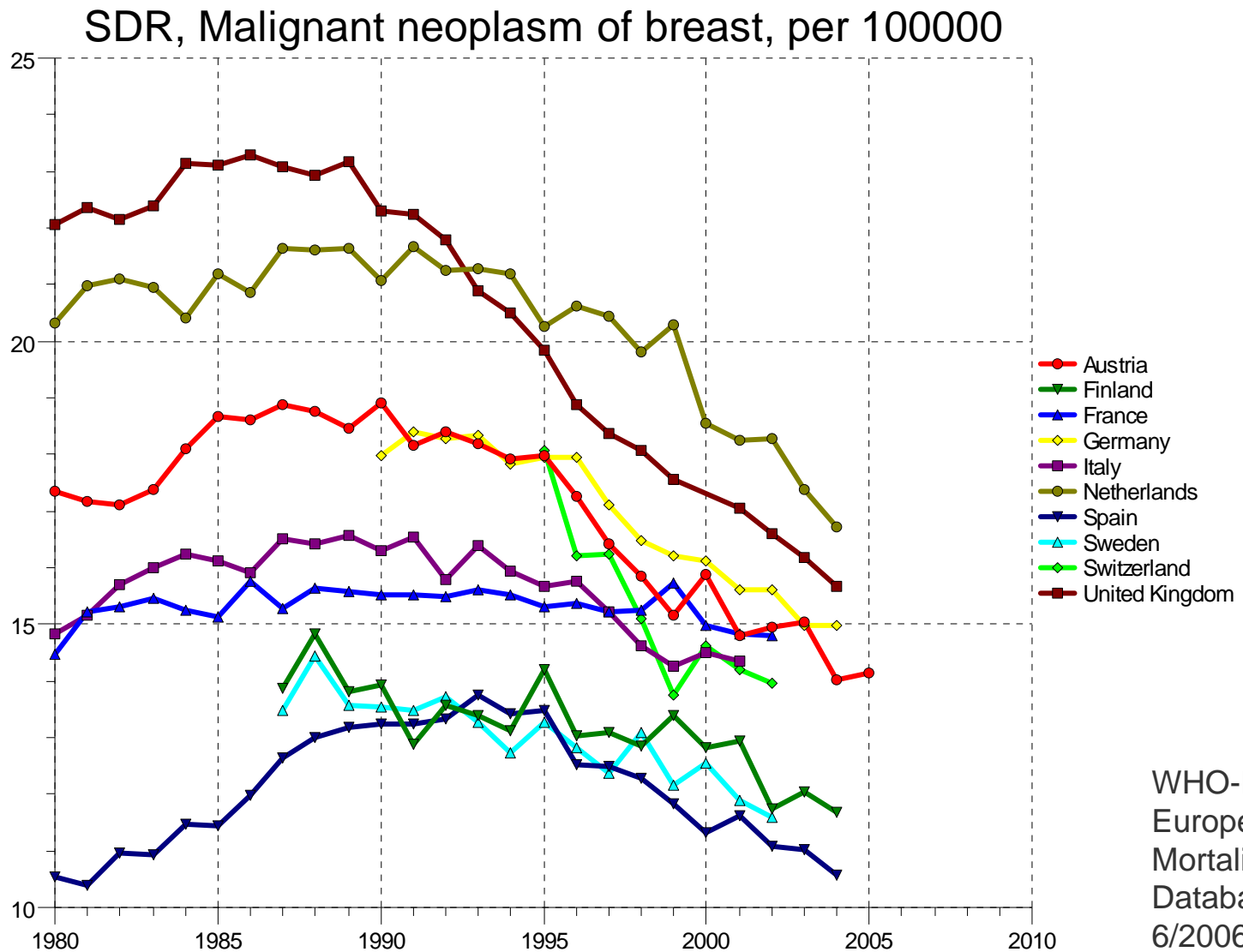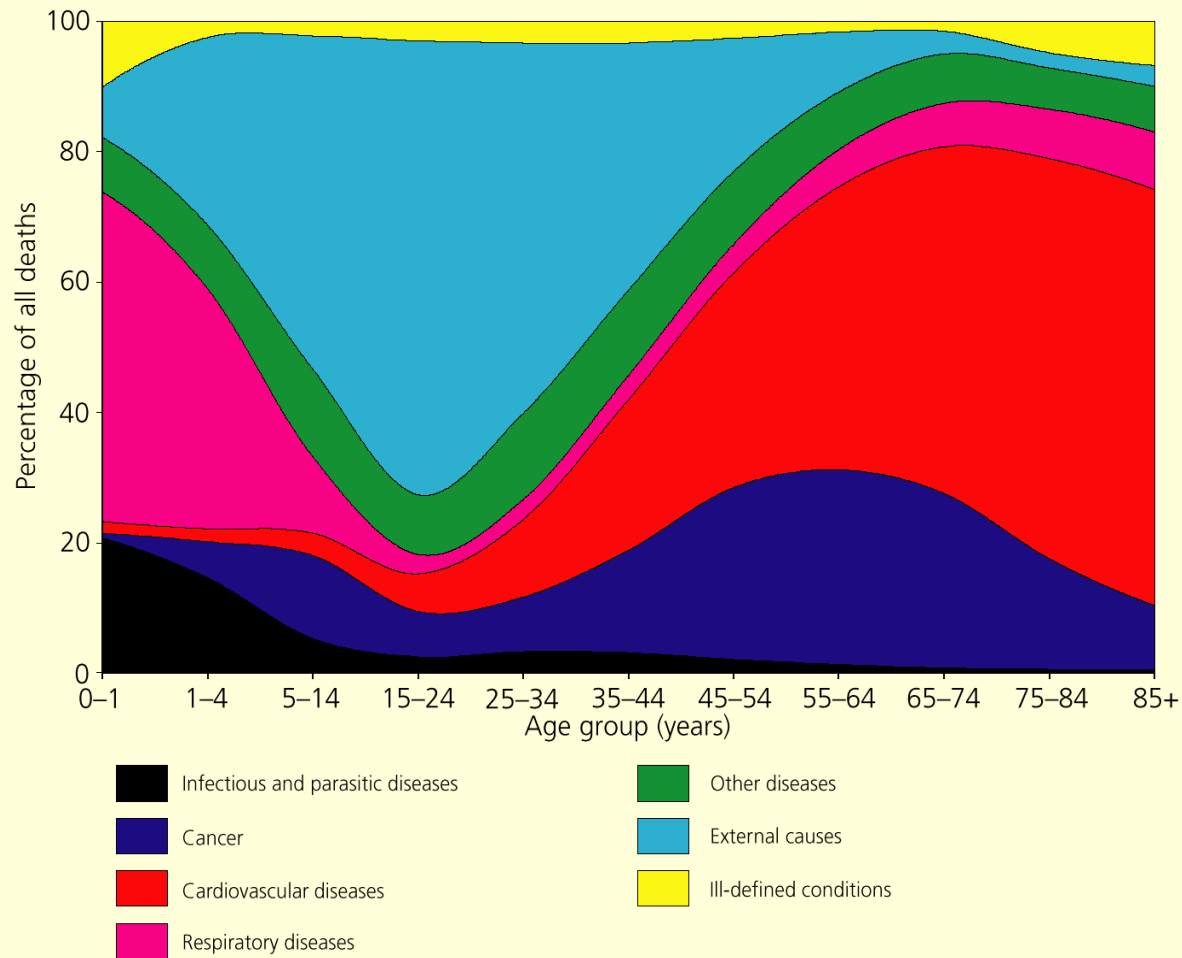WHO-Euro: European Mortality Database 6/2006

Fig. 5. Main causes of death by age in the European Region, mid-1990s

Source: data from the WHO Regional Office for Europe.

Cumulative risk of disease

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Table 1. Chances of the Development of and Death from Breast Cancer within the Next 10 Years.*

Age	Cases of Invasive Breast Cancer	Death from Breast Cancer	Death from Any Cause
		no./1000 women	
40 Yr	15	2	21
50 Yr	28	5	55
60 Yr	37	7	126
70 Yr	43	9	309
80 Yr	35	11	670

* Rates for breast cancer and death from breast cancer were calculated on the basis of data from Feuer and Wun[6]; rates of death from any cause were calculated on the basis of data from Anderson and DeTurk.[7]

Given an 60-year old woman, her chance of dying from breast cancer in her next decade of life is: 7/1000=.07

Or 0,7%

Her chance of dying from any cause is 126/1000=12,6%

Adopted from Cobb 2004

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Dilemma: which information to what extent

Example for 50-60 year old woman, observation period 10 years, cohort of 1000 women (Mühlhauser 2000)

Save 8300 lives per year or Reduce your risk by 25%

	Without Mx	With biennial Mx
Deaths from breast cancer	8	6
Died from other causes	72	74
Living	920	920
Diagnosis breast cancer	25	30
No diagnosis breast cancer	975	970
All screening ammographies		5000
False positives		200
Biopsy because of false positives		60

Screened   Not Screened

1000

300 False-positive mammograms

150 Procedures because of mammograms

15 New breast cancers 15
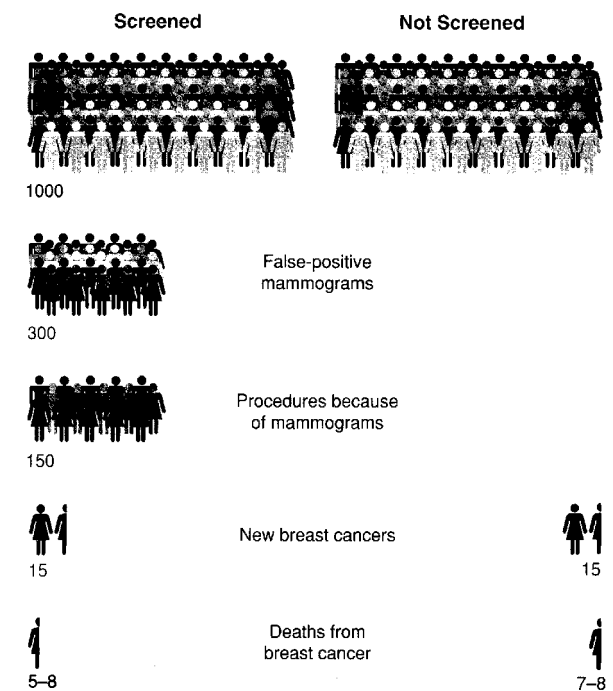
5–8 Deaths from breast cancer 7–8

Figure 8.8. Weighing benefit and harm from screening. What happens during a decade of annual mammography in 1000 women starting at age 40.

Misconception about efficacy of mammography screening: a public health Dilemma

Chamot E, Perneger TV: J Epidemiol Community Health 2001: 55:799-803

895 randomly selected women aged 40-80 years, free of breast cancer, general population of Geneva, Switzerland, written questionnaire

In your opinion, does mammography screening prevent death from breast cancer in women over age 50	Number	%	95% CI
No	23	2,6	1,6;3,8
Yes, about one quarter of deaths	173	19,3	16,5;21,7
Yes, about one half of deaths	266	29,7	26,3;32,3
Yes, about three quarters of deaths	200	22,3	19,3;24,8
Don´t know	233	26,0	22,8;28,6

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Influencing contradictions:

Effectiveness presentation and participation rate?
Transparency and Indemnity insurance?
Sensitivity and specificity?

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Conclusions

Mammography screening as a long, winding road
Germany´s starting position not that bad
Early indicators are promising
Difficult communication issues
Transparency is key to success: but to what extent
Public discourse reg. program still in its beginnings

Thank you for your attention!
bgibis@kbv.de

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Evaluation of Mammographic Tests in the Randomized screening trials

- Sensitivity: using as denominator the total number of breast ca cases diagnosede in a given interval: 71% - 96% in the first round for a 1 year interval. Sensitivity was higher in women $\geq$50 years old

- Specificity: 94% - 97%

- PPV: 2% - 22% for abnormal results requiring further evaluation, & 12% - 78% for results requiring biopsy.

- Estimates from community settings suggest a continuous increase in PPV with age.

- Humphrey LL, Ann Intern Med 2002; 137: 347-360